

Exhibit D

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1 carry? And we are not going to take a real
2 conservative -- well, we are not going to go with
3 a really low load without, you know, having a lot of
4 justification for that.

5 So in this case we wanted to be conservative
6 in the sense of worst case; so what we know is that
7 if I take a piece of TVTTM mesh and pull on it, there
8 comes a time where if I let go of the mesh, I pull on
9 it and let it go, it goes back to its original shape.
10 And that if I keep applying a load and I let go, then
11 it does go back to its original length. And that's
12 called a yield point in engineering testing.

13 We know that the TVTTM mesh just doesn't
14 deform like that in clinical use. It doesn't look
15 like that after you place it. And if it were to
16 do that after it has been placed and the patient has
17 gone home and has resumed her life, then what would
18 happen is every time that mesh sees a load, if it is
19 already permanently deformed and it is already
20 lengthened, the patient would go back to being
21 incontinent because now the mesh is too long and it
22 is not supporting the urethra. And we know that
23 doesn't happen because we have got years -- eleven
24 years, seventeen years of clinical data to show that
25 the TVTTM works. It is a durable cure.

26 Q. Now, the next sentence says:
27 "This fixation force is more than
28 100 grams greater than the mean tension

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1 sustained by a fascial sling following
2 pubovaginal sling surgery in a published
3 study."

4 And then there's a footnote three.

5 A. Uh-huh.

6 MR. GAGE: If you could highlight footnote
7 three, Marc.

8 BY MR. GAGE:

9 Q. And we see here a reference to a study.

10 All right. So would you explain to us the
11 final highlighted sentence and the highlighted
12 footnote, what that means.

13 A. Yeah. So we had an engineering and medical
14 justification for using 164 as our worst caseload.
15 We know that it doesn't go beyond that.

16 Back in 2005 a study was published by Lin,
17 et al., where they actually instrumented a fascial
18 sling during an SUI surgery in ten patients, and then
19 they had the patient cough while the sling was on
20 there. They had a force gauge on it, and they
21 measured the force that the sling saw. And the
22 forces that they measured during the cough at various
23 bladder volumes and with the patient lying flat and
24 with the patient elevated some -- not so much that
25 she slid off the table but elevated some -- they
26 found that the largest force seen was fifty grams,
27 which is pretty low force.

28 If they measured fifty grams in an actual

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1 live patient during a hard cough and we are testing
2 to more than 100 grams higher than that, we are at
3 164, then we are pretty sure the load we are applying
4 is -- is much worse than the sling we'll see in the
5 body and that is the load that we use to make this
6 assessment. We're going to go worst case. We have
7 got to make sure our sling can do this.

8 Q. In terms of pounds and ounces, what does
9 fifty grams equate to?

10 A. So fifty grams is less than two ounces.

11 Q. All right.

12 MR. GAGE: You can take that down, Marc.

13 Thank you.

14 BY MR. GAGE:

15 Q. All right. Now, Ms. Elbert, I want to ask
16 you about -- you mentioned it, I believe, yesterday
17 briefly. I want to go back to TOPA.

18 Can you remind the jury what TOPA was.

19 A. So TOPA was a project I worked on after we
20 launched Abbrevio. TOPA was our attempt to use
21 a partially absorbable mesh, as opposed to the
22 Prolene® mesh on our other TVTTM products, which pure
23 Prolene®, it doesn't resorb, but a partially
24 absorbable mesh in a TVTTM-O like procedure.

25 Q. Okay. And what is the difference -- what is
26 the difference between TOPA mesh and the Prolene® mesh
27 that is used in, for example, Abbrevio?

28 A. Uh-huh. So our regular TVTTM mesh is a knit

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1 mesh. What we do is we take a strand of clear
2 Prolene® and a strand of blue Prolene®. We gently
3 twist them together, and we knit our mesh. Because
4 it is all Prolene®, that's -- the mesh you start with
5 is the mesh you end with.

6 And for the partially absorbable mesh, what
7 we did is we kept our strand of blue Prolene® and now
8 we twisted it with a strand of clear Monocryl™, which
9 is an absorbable -- it is a material we use in
10 sutures, and we knit the mesh out of that. Same kind
11 of knit constructions. Same kind of pore size. But
12 now, instead of two strands of Prolene®, it is one
13 strand Prolene®, one strand Monocryl™ knitted into
14 our mesh and that was a concept we were pursuing for
15 SUI.

16 Q. All right. And you were the project leader
17 for TOPA?

18 A. Yes.

19 Q. Just as you were for the Abbrevio?

20 A. Yes.

21 Q. Okay. What was the overall purpose or goal
22 of TOPA? What were you trying to accomplish?

23 A. So this was where we -- we were looking
24 at -- we know the TVTTM mesh works. We have great
25 clinical history. We offer those products today.
26 But we also, sort of philosophically, like the idea
27 of less is more.

28 So with Abbrevio we give surgeons the option

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1 of leaving less mesh in the patient because it is
2 shorter, but it is the same mesh; so TOPA was our
3 idea, well, what if we can leave less mesh in the
4 patient -- the same length, but less eventual
5 material after the MonocrylTM resorbs. And the
6 MonocrylTM resorbs pretty quickly. It takes weeks or
7 months. And then just the Prolene[®] piece is left
8 behind.

9 Q. All right. The jury has heard about the
10 a mesh called UltraproTM.

11 A. Uh-huh.

12 Q. Are you familiar with that mesh?

13 A. Yes.

14 Q. That is an Ethicon mesh; correct?

15 A. Yes.

16 Q. What is UltraproTM made of?

17 A. So UltraproTM is also made of Prolene[®] and
18 MonocrylTM.

19 Q. And the jury has also heard of Vypro[®]?

20 A. Yes.

21 Q. Have you heard of Vypro[®]?

22 A. Yes.

23 Q. Vypro[®] is another Ethicon mesh?

24 A. Yes.

25 Q. What is Vypro[®] made of?

26 A. Vypro[®] is made out of Prolene[®] plus Vicryl.

27 Q. Now, Ms. Elbert, explain to the jury what
28 testing, if any, you personally participated in with

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1 respect to the TOPA mesh.

2 A. So as part of the development of TOPA, we
3 were doing development on the mesh itself. We were
4 working with the people who were knitting the mesh to
5 develop that process, and then we were testing a lot
6 of samples to make sure that our process -- you know,
7 the various ways, how fast you knit it, how hot you
8 kneel it, how you scour or clean the mesh after. How
9 long you can store the mesh, which has an absorbable
10 component. You have to protect it from light and
11 from moisture; so, you know, all those different
12 parameters, what impact that has on the material
13 properties of the mesh itself. And then we had to do
14 testing on not just the mesh as a component, but the
15 mesh as used in our basically O-like procedure,
16 Obturator-like procedure.

17 Q. And at some point, the company submitted
18 a 510(k) application for TOPA; correct?

19 A. Yes, we did.

20 Q. And what happened with that?

21 A. The FDA came back with a series of
22 questions. Concurrently with that, we were
23 continuing our development work and looking towards
24 a clinical study.

25 When the FDA came back with questions, we
26 then recognized that we were having usability issues
27 not with the mesh, but the mesh as used in that
28 product; so we were continuing on with our

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1 development work.

2 We ended up -- so we requested an extension
3 from the FDA to respond to their questions, and then
4 we ended up withdrawing the submission.

5 Q. Okay. And what generally were the questions
6 that were being asked by FDA with regard to TOPA?

7 MR. CARTMELL: Objection, Your Honor.
8 Hearsay.

9 MR. GAGE: I can rephrase it.

10 THE COURT: Yeah. Rephrase it.

11 BY MR. GAGE:

12 Q. What were the issues that were being raised
13 by the FDA with regard to TOPA?

14 MR. CARTMELL: Same objection, Your Honor.

15 THE COURT: Overruled.

16 THE WITNESS: So the FDA was asking us if we
17 had human clinical data, and at the time of
18 submission we did not; however, we were preparing
19 a clinical study at that time.

20 They also had some questions around the
21 materials used in the mesh and -- yeah. Just
22 others -- some general questions, but predominantly,
23 it was around a request for clinical data.

24 BY MR. GAGE:

25 Q. And the issues with regard to the materials
26 used in the mesh, what -- what were those issues?

27 A. Yeah. So they were asking us for some
28 additional background data on the MonocrylTM and on

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1 the -- how we knit the mesh, those kinds of things.

2 Q. Okay. Now, were cadaver labs -- you
3 indicated that concurrently with the submission of
4 the 510(k) you were also doing some additional
5 testing.

6 Did you do any cadaver lab testing on TOPA?

7 A. Yes, we did.

8 Q. Can you describe that testing -- well, first
9 of all, let me ask you this.

10 Were you personally involved in that?

11 A. Yes, I was.

12 Q. Okay. Can you describe to the jury the
13 testing -- the cadaver testing for TOPA.

14 A. So we took TOPA prototypes and went into
15 a cadaver lab, started to place them, and then were
16 surprised by the results that we had. It was -- the
17 mesh, you could place it while it was still in
18 a sheath.

19 I don't have an O in front of me, but while
20 it is still covered in this plastic sheath we could
21 do the procedure. And then at the end of the
22 procedure you have to pull the sheath out to leave
23 the mesh behind. And those sheaths were really hard
24 to pull off, and we had not experienced that before.

25 Q. How many different -- well, did you do
26 multiple cadaver labs?

27 A. Oh, yes.

28 Q. How many?

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1 A. We did at least six cadaver labs.
 2 Q. And what was the purpose of each of those
 3 six cadaver labs?
 4 A. Well, when this first happened we thought,
 5 okay. Maybe we had a weird prototype. Maybe the
 6 surgery wasn't quite right. Let's try it again; so
 7 we tried it several times. Sometimes it worked
 8 better than other times. But every time we placed
 9 it, we had issues pulling off the sheath. And from O
 10 and Abbrevio we were used to that sheath just kind of
 11 slipping right out. You don't really even think
 12 about it.

13 So we would make new prototypes, trying new
 14 things. Was it the sheath? Was it the mesh? Had
 15 they been out in air too long? Had they gotten wet?
 16 Did they need to be wet? We tried all different
 17 kinds of things to address this. And, of course, at
 18 this point we knew that everything else was on hold.
 19 We were not submitting. We were not proceeding. We
 20 were trying to figure this out.

21 Q. Okay. And what was the difference, if any,
 22 between the mesh that you were using in TOPA versus
 23 the mesh that you were using in Abbrevio and TVTTM-O?

24 A. Yeah. So the difference would be the
 25 addition of that MonocrylTM -- or, actually, a
 26 substitution of half the Prolene® for MonocrylTM.

27 Q. Which is the absorbable part?

28 A. Exactly.

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1 Q. Okay. Were you or the company ever able to
 2 determine what the problem was and why you couldn't
 3 get it to work in the cadaver labs?

4 A. So we worked on that for about another year
 5 making samples, trying to test them. At this point
 6 we weren't testing on cadavers anymore. We made
 7 a benchtop kind of fixture to try to figure this out,
 8 made a lot of product, tried all different kinds of
 9 parameters. We could not really get to the bottom of
 10 what the issue was of this partially absorbable mesh
 11 in an obturator-type procedure in a sheath; so that
 12 was our final conclusion of, okay. We don't know
 13 why. If you are going to do a partially absorbable
 14 mesh right now, we don't have a way to place it as an
 15 obturator product.

16 Q. Now, as part of your work on TOPA, did you
 17 have an occasion to test laser-cut and mechanical-cut
 18 mesh?

19 A. Yes.

20 Q. Okay. Explain to the jury why you were
 21 conducting those tests.

22 A. So while we were developing the mesh we
 23 needed to set requirements for it of how should it
 24 act. And one of their requirements we had on it was
 25 that it shouldn't be so different from the mesh we
 26 currently sell.

27 Now, we only sell one mesh. It is the TVTTM
 28 mesh. But we sell it cut two different ways. It is

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1 the same mesh. It comes into the plant on the same
 2 roll. Some of it gets made into laser-cut product.
 3 Some of it gets made into mechanical-cut product. It
 4 is just a process step.

5 But we know that at high loads and at high
 6 elongations laser cut and mechanically cut start to
 7 act a little differently. At low loads they are
 8 identical; so it didn't make much sense to just look
 9 at the low-load range. But when we do benchtop
 10 testing, we always test our stuff to extremes, and so
 11 we tested this. We had a requirement that the mesh
 12 needed to act kind of within the range of what we
 13 think were mechanically and laser-cut mesh.

14 Q. And so this work was being done by you for
 15 project TOPA; correct?

16 A. Yes.

17 Q. Okay. Was the mesh that you were using
 18 during this testing the same mesh that would have
 19 been in the Abbrevio -- or at least some of the mesh
 20 that you would have been testing, would it have been
 21 the same mesh in Abbrevio?

22 A. Yes. It is all the same basic mesh.

23 Q. And why was this testing important? Why was
 24 it important enough for you to do?

25 A. We have the gold standard product. TVTTM
 26 mesh is -- that's the product that everyone else
 27 compares themselves to. It is the product the FDA
 28 compares to. It's the gold standard. You don't mess

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1 around with that lightly. It is a very effective
 2 product. It has been used around the world.

3 So we have a real legacy there. And for us
 4 to come out with a new mesh, it has got to meet
 5 a really high standard for us to say, all right.
 6 This is as good as TVTTM; so we did a lot of testing
 7 to make sure that this mesh would be at least as good
 8 as TVTTM.

9 Q. And what was your role in that testing?

10 A. So I -- as project lead, I received all of
 11 the data, I analyzed the data. And after we did
 12 testing for another good year or so, I was the one
 13 who wrote the completion report on everything we
 14 found out and didn't find out.

15 Q. All right. Is it fair to characterize this
 16 testing as elongation testing?

17 A. Yes.

18 Q. And describe for the jury what elongation
 19 testing is.

20 A. Okay. So when you do a tensile test, you
 21 get your mesh, you clamp it top and bottom, and you
 22 pull; so you can either apply a load -- you know,
 23 a force -- and measure how much your mesh stretches
 24 or elongates or you can apply an elongation or
 25 a displacement and measure the force it took to get
 26 there. You apply one and you measure the other.

27 So it doesn't particularly matter if I have
 28 a mesh this long or a mesh this long or a mesh this